



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Weaver et al. SERIAL NO: 09/659,103

ART UNIT: 1644

EXAMINER: Ewoldt, G.

FILED:

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TITLE:

WATER-SOLUBLE GLOBULIN CONCENTRATE FOR IMPROVING

GROWTH IN ANIMALS

132 DECLARATION OF ERIC M. WEAVER

Commissioner of Patents and Trademarks Washington, D.C. 20231

NOV 2 9 2002
TECH CENTER 1600/2000

Dear Sir:

I, Eric M. Weaver hereby declare the following:

- 1. I am a named inventor on the above-identified application. As such, I am familiar with the prosecution including the Examiner's Office Action dated May 20, 2002 and the following references cited by the Examiner: US Patent No. 4,816,252 in view of Japanese Patent No. 61-132143 (abstract only) and US Patent No. 4,623,541.
- 2. I understand that the Examiner has placed a rejection on the case over the above-identified references under 35 U.S.C. § 103(a).
- 3. That a test was performed by me to evaluate the effect of a globulin concentrate from animal plasma, included in the drinking water of weaned pigs consuming a diet containing 5% globulin concentrate from animal plasma. Globulin concentrate from animal plasma was added to the drinking water at 0%, 1.25%, 2.5% and 5.0% (Table 1). Compared to the control pigs, the addition of 2.5% globulin concentrate to the drinking water improved daily gain 297% and daily feed intake was increased 133%. It is most important to note that this response was observed in pigs consuming a diet supplemented with plasma

proteins. This magnitude of response is well outside the expected response to plasma when included in the dry feed.

Table 1. Summary of Initial 4 days of experiment

Concentratio	0	1.25%	2.50%	5.0%	SEM
n					
D 0-4					
ADG, kg	0.042^{a}	0.105^{b}	0.125^{b}	0.088^{ab}	0.016
ADFI, kg	0.069ª	0.092^{b}	0.092^{b}	0.094^{b}	0.006
ADWI, mL	506 ^a	650 ^b	661 ^b	643 ^b	16

ab = P < 0.05

- 4. US Patent '252 as stated by the Examiner differs from the claimed invention in that it does not teach the specific use of animal plasma-derived globulins to promote weight gain and growth nor administration of the globulins in specific concentrations, i.e., at least 15% IgG, in a dispersed concentration of about 0.375 to about 3.0% by weight, and a concentration of about 0.1-0.75% IgG by weight.
- 5. Similarly, the effect seen in Japanese Patent No. JP61132143 (abstract only) was used in an animal <u>feed</u> comprising a globulin-containing substance, an antimicrobial agent, and in common feed.
- 6. Two trials were conducted with broiler chicks to evaluate the effect of adding plasma protein to the feed or water. The first experiment was designed as a 2 X 2 factorial with 3.5% plasma in the feed and 1.35% plasma in the water. Growth rate of male chicks (Ross x Ross 308) was measured for 7 days. Daily gain was improved when plasma was included in the water but not when it was included in the feed (Table 2).

Table 2

Table 2.					
Feed	-	+	-	+	SEM
Water	-	-	+	+	
D 0-7, ADG,	18.95ª	19.21 ^a	20.97 ^b	20.41 ^b	0.26

$$abc = P < 0.05$$

The second trial was designed similar to the first. Addition of plasma to the feed improved growth rate (6.8 %) but not to the extent of adding plasma to the water (22.4%; Table 3).

Table 3.							
Feed	-	+	-	+	SEM		
Water	-	-	+	+			
D 0-7, ADG,	16.22ª	17.32 ^b	19.86°	18.98 ^c	0.32		
g							

abc = P < 0.05

- 7. That the above tests demonstrates addition of plasma protein to the feed of either weaned pigs or chicks improved growth performance. However, addition of plasma protein to the <u>drinking water</u> resulted in improvements in growth performance well beyond the expected plasma protein response.
- 8. The undersigned further declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Date: _// /8 / 02

Eric M. Weaver